REMARKS

Claims 40-44 have been canceled as being drawn to a non-elected invention. Claims 18-23, and 45-53 remain in the application.

The specification has been amended at page 1, line 8 to update the status of the "parent" application, namely, to provide the number of the issued patent.

The specification has also been amended to add a paragraph at page 34, between lines 14 and 15, to add text to the specification conforming to Claims 18 and 19 as originally filed. The Claims as originally filed are, of course, part of the Applicant's original disclosure; and the specification may be amended to conform to the Claims as originally filed, without raising a question of new matter. See, e.g., M.P.E.P. §§ 608.01(l) and 608.04 (first paragraph).

Enclosed is a check for $465 for a one-month extension of time as a small entity, to extend the time for response from June 26, 2003 to September 26, 2003. (37 C.F.R. § 1.136(a)(3)). If this amount is incorrect, please refer to the Deposit Account Authorization previously filed for this application. If any additional extension of time is required, please consider this paper a petition for the total extension of time required.

Reexamination and reconsideration of the application, as amended, are respectfully requested.

Clerical Matters

Applicants wish to bring four minor clerical matters to the Office's attention:

(1) An apparent typographical error appears in Box 6 of the March 26, 2003 Office Action Summary (PTO-326), in that the Claims listed there did not fully correspond with the Claims that were examined and rejected in the text of the March 26, 2003 Office Action.

(2) Also, it appears that Box 15 on the same form PTO-326, concerning domestic priority under 35 U.S.C. §§ 120 or 121, was inadvertently left unchecked. (Box 14,

concerning domestic priority under 35 U.S.C. § 119(e), was checked by the Office, and it should remain checked.) See the June 7, 2001 Preliminary Amendment, as well as the present amendment to the specification at page 1, line 8.

(3) There is an apparent typographical error on page 2, of the March 26, 2003 Office Action, paragraph 3. The reference to the "Information Disclosure Statement filed January 10, 2002" is understood instead to refer to that which was filed on June 7, 2001.

(3) The Office Action dated March 26, 2003 was not received in the undersigned's office until April 28, 2003, over one month later. The paper of the Office Action was yellowed and quite brittle, as if it had been irradiated. While the undersigned has previously seen examples of incoming materials at the Office being irradiated, this is the first time that the undersigned can recall seeing outgoing materials originating from the Office that had apparently been irradiated.

The Office is not being requested to re-mail the March 26, 2003 Office Action, nor to set a new period for response. Rather, this information is being brought to the Office's attention in case there might be any practices in place that might be inadvertently delaying outgoing mail, or that might be causing the unintended irradiation of outgoing mail.

The Restriction Requirement

For the record, it is Applicants' position that the rationale presented in the March 26, 2003 Office Action does not adequately support the restriction requirement. Nevertheless, to expedite the prosecution of this patent application, Applicants acquiesce in that restriction requirement, and have canceled the Claims drawn to non-elected Group II. All currently pending Claims correspond to Group I, whose election is affirmed.

The § 112, Second Paragraph Rejections

Claims 18-21 were rejected under 35 U.S.C. § 112, second paragraph as being indefinite.

Before discussing this rejection in detail, it should first be recalled that a claim is definite if its scope is clear. It appears, however, that the Office has instead objected merely to the breadth of certain limitations. If the metes and bounds of a claim are clearly ascertainable, then the claim, no matter how broad, may not properly be rejected under § 112, second paragraph. As stated by the Court of Customs and Patent Appeals, one of the two predecessor courts to the Court of Appeals for the Federal Circuit, if each of the limitations of a claim is definite, then the claim is definite and may not be rejected under section 112, second paragraph. *In re Goffe*, 526 F.2d 1393, 1397-98; 188 USPQ 131, 135 (CCPA 1975).

A Claim may not be rejected under § 112, second paragraph merely because it is broad. Breadth and indefiniteness are logically separate concepts. Hypothetically, a Claim may be narrow, but indefinite; or it may be broad, but definite. The former would be properly rejected under § 112, second paragraph, while the latter would not. A proper § 112, second paragraph rejection may be based only on a lack of definiteness, not on breadth.

The Office's objections to individual Claims are discussed below.

Claim 18

It is difficult to understand the Office's comments concerning Claim 18 as objecting to anything other than breadth. The Office has not shown that Claim 18 is in any way indefinite: "The specification does not clarify claims 18-19 and 21, and merely broadly refers to any dipeptide [outside the express negative limitation] as within the invention. Applicant is asked to amend the claims to distinctly claim: which polymers of compounds

make up the dipeptide chiral micelles . . . ." (March 26, 2003 Office Action, p. 4) As previously discussed, breadth does not mean indefiniteness.

Claim 18 indeed claims polymerized dipeptide chiral micelles broadly, outside the express negative limitation. The specification clearly explains the components and features of the recited polymerized dipeptide chiral micelles, and confirms that Claim 18 should be given a broad interpretation:

> ***Micelles***
>
> Surfactants, molecules having both hydrophilic and hydrophobic groups, associate with one another in polar solvents such as water to form dynamic aggregates known as "micelles." A micelle typically takes roughly the shape of a sphere, a spheroid, an ellipsoid, or a rod, with the hydrophilic groups on the exterior and the hydrophobic groups on the interior. The hydrophobic interior provides, in effect, a hydrophobic liquid phase with solvation properties differing from those of the surrounding solvent. Micelles form when the concentration of the amphophilic molecules in solution is greater than a characteristic value known as the critical micelle concentration (**"CMC"**).
>
> Specification, page 3, lines 14-21.
>
> ***Chiral Micelles***
>
> An important application of micelles is their use in chiral recognition and separation. Chiral surfactants have been used to form micelles having distinct chiral properties. The resulting chiral microenvironment has been shown to exhibit selective interactions with different enantiomers in solution.
> . . .
>
> In addition to the equilibrium between micelles and ligands, there is also a dynamic equilibrium between surfactant molecules and micelles. "Conventional" micelles are dynamic aggregates of surfactant monomers; the monomers exist in equilibrium between aggregation in micelles, and being free in solution as smaller aggregates down to monomers. Because the difference in interactions between a chiral micelle and two enantiomers is often very small, these dynamic equilibria may interfere with the separation of enantiomers. See the schematic diagram of Figure 1(a), in which an asterisk represents a chiral center, and S represents the solute.

Specification, page 4, lines 1-17.

Polymerized Micelles

Polymerized surfactant aggregates, or polymerized micelles, were first developed in the late 1970's and early 1980's. Compared to otherwise identical non-polymerized micelles ("conventional micelles"), polymerized micelles exhibit enhanced stability, enhanced rigidity, and better control over micelle size. The covalent bonds between surfactant monomers essentially eliminate the dynamic equilibrium between surfactant monomers and "conventional" micelles, simplifying and enhancing complexation between micelle and ligand.

An important advantage of polymerized micelles is that they have no critical micelle concentration (**"CMC"**). Because the individual surfactant monomers in a polymerized micelle must associate with one other, micelles form regardless of how low their concentration is. By contrast, with non-polymerized micelles the concentration of the surfactant must be higher than the CMC for a significant concentration of micelles to form.

Specification, page 4, line 24 to page 5, line 3.

Polymerized Chiral Micelles

Polymerized chiral micelles eliminate much of the complex dynamic behavior otherwise associated with micelles. Polymerized chiral micelles often have stronger chiral recognition properties than do otherwise-identical, "conventional" or non-polymerized chiral micelles.

Specification, page 5, lines 27-30.

Dipeptide chiral micelle polymers in accordance with the present invention may be used as mobile phase additives for chiral separations in capillary electrophoresis, or in micellar liquid chromatography under reversed phase conditions. Our method of preparing chiral micelle polymers is easy to implement, and readily lends itself to use with a variety of polymers having different structures and degrees of chirality, which can be manipulated to enhance the chiral separations for particular analytes. Using synthetic means known in the art, the chiral centers can be moved to different locations along the individual monomers, and the number of chiral centers per micelle can be increased or decreased by using micelles with higher or lower aggregation numbers, respectively. Different monomer lengths may readily be generated through means known in the art. Fatty acid-type monomers terminating in double bonds are preferred, because such monomers may be used in the synthetic scheme described above with minimal modifications to the synthesis.

Specification, page 33, lines 9-19.

The synthetic scheme outlined above is a fairly general one in which the final steps may be modified to obtain a surfactant monomer with a different chiral center. For example, if π-π interaction is desired at the chiral center, phenylalanine, tyrosine, or tryptophan could be used in place of valine in the monomer synthesis. Histidine could also be used where a π-π interaction is desired, with care taken to "protect" one of the two amino groups of the histidine ring during synthesis.

In general, any unsaturated fatty acid may be substituted for undecylenic acid to serve as the "backbone" for the chiral monomer. Examples of naturally-occurring, readily available unsaturated fatty acids include palmitoleic acid, oleic acid, linoleic acid, linolenic acid, arachidonic acid, caproleic acid, elaidic acid, brassidic acid, erucic acid, nervonic acid, and vaccenic acid. The chemistry of attaching the chiral group to these unsaturated fatty acids, and their polymerization into chiral micelle polymers, will be essentially similar to that described above. Although preferred, the "backbone" of the monomer need not be a fatty acid or fatty acid derivative. Other amphophilic molecules could also be used for the "backbone," using methods known in the art of organic synthesis for attaching chiral groups to the backbone, and for polymerizing the chiral surfactant monomers into micelle polymers.

An example of the present invention is a polymerized dipeptide chiral micelle, wherein said polymerized dipeptide chiral micelle is not a polymer of a compound selected from the group consisting of *N*-undec-10'-enoyl-L-prolyl-L-glutamic acid, *N*-undec-10'-enoyl-L-methionyl-L-glutamic acid, and *N*-undec-10'-enoyl-L-phenylalanyl-β-alanine. Another example of the present invention is polymerized dipeptide chiral micelle as just described, wherein said micelle comprises a polymer of monomers, wherein each of said monomers comprises an unsaturated hydrocarbon chain linked to a chiral dipeptide.

Various amino acids can be substituted for valine to synthesize other surfactant monomers analogous to L-SUVV, surfactant monomers that can then be polymerized to form other micelle polymers. Any amino acids may be used as the chiral groups, including alanine, valine, leucine, isoleucine, proline, tryptophan, phenylalanine, methionine, glycine, serine, threonine, tyrosine, cysteine, glutamine, asparagine, lysine, arginine, histidine, aspartic acid, glutamic acid, and modified amino acids.

Specification, page 34, lines 1-19 (as amended).

The recited excerpts from the specification clearly explain the components and features of the recited polymerized dipeptide chiral micelles, and confirm that Claim 18 should be given a broad interpretation.

It is respectfully submitted that Claim 18 is definite.

Claim 19

The only comment offered by the Office concerning dependent Claim 19 that did not also apply to independent Claim 18 (discussed above) was the following: "Applicant is asked to amend the claims to distinctly claim: . . . what monomers form the polymers and where the hydrocarbon chain is linked on the specific dipeptide . . . ." (March 26, 2003 Office Action, page 4).

To answer the first question, what monomers form the polymers, Claim 19 clearly states "each of said monomers comprises an unsaturated hydrocarbon chain linked to a chiral dipeptide." While this limitation may be broad, it is clear. Section 112, second paragraph requires no more.

To answer the second question, where the hydrocarbon chain is linked to the dipeptide, the location of the linkage is not a limitation of Claim 19. Claim 19 requires only that the two components be linked. Again, while this limitation may be broad, it is clear. If the two components are present in the monomer (i.e., unsaturated hydrocarbon chain and chiral dipeptide), and if the two components are linked, then this limitation is satisfied.

It is respectfully submitted that Claim 19 is definite.

Claim 20

The Office's comments concerning dependent Claim 20 (March 26, 2003 Office Action, p. 5) are not understood. The Office's comments appear to place undue emphasis on the negative limitation of independent Claim 18. While that negative limitation is, of

course, incorporated into Claim 20, the Office's comments concerning the negative limitation are not understood.

Claim 20 clearly states that "each of said polymerized chiral micelles is a micelle as recited in Claim 18." Thus each of the different micelles that is recited as being part of the mixture of Claim 20 must satisfy the limitations of Claim 18 -- including, but not limited to, the negative limitation of Claim 18. Placing another interpretation on the negative limitation is not suggested by Claim 20 -- for the simple reason that Claim 20 makes no express reference to the negative limitation. It is not understood why the Office has raised any questions about the negative limitation of independent Claim 18 in the context of Claim 20.

The Office also asked where support in the specification for Claim 20 might be found. Although support in the specification is not generally a § 112, second paragraph issue, the Office's attention is respectfully directed to the specification, for example, at page 33, lines 20-24.

It is respectfully submitted that Claim 20 is definite.

Claim 21

The only comment offered by the Office concerning dependent Claim 21 that did not also apply to independent Claim 18 (discussed above) was the following: "Applicant is asked to amend the claims to distinctly claim: . . . what specific 'different' dipeptide monomers form the copolymers of the micelles . . . ." (March 26, 2003 Office Action, page 4).

The Office did not explain why this limitation was said to be indefinite. Claim 21 reads as follows: "A micelle as recited in Claim 18, wherein said micelle comprises a co-polymer of a plurality of different dipeptide chiral surfactant monomers." As this language suggests, the limitation added by Claim 21 requires that the micelle comprise a co-polymer, i.e., a polymer formed of different monomers. Those different monomers are

different dipeptide chiral surfactant monomers. Again, while this limitation may be broad, it is clear.

Also, the March 26, 2003 Office Action at page 4, lines 10-14 refers to "claim 22." From context, it appears that this is a typographical error, and that "claim 21" may have been intended instead. The Office's remarks here again appear to place undue emphasis on the negative limitation of independent Claim 18. On this point, Applicants refer to the remarks given above concerning Claim 20, which will not be repeated in the interest of brevity.

It is respectfully submitted that Claim 20 is definite.

Some Remarks Concerning Issued Patent 6,270,640

The "parent" application has now issued as U.S. Patent 6,270,640. The limitations to which the Office has objected in the present application generally have one or more counterparts in the limitations of the issued claims of the '640 patent. See, e.g., Claims 1, 11, 12, and 13 of the '640 patent. (Applicant is not suggesting that the claim scope is identical, but rather that the limitations in question in the present application generally have counterpart limitations in the claims of the issued patent.)

The Office has previously determined that the Claims of the '640 patent are patentable, which means among other things that each of those Claims was definite. By analogy, it should follow that the limitations at issue in the present application are also definite.

§ 112, Second Paragraph Summary

It is respectfully submitted that all Claims are definite as written, and that all § 112, second paragraph rejections should be withdrawn

The § 112, First Paragraph Rejections

Claims 18-21 were rejected under 35 U.S.C. § 112, first paragraph as lacking a written description in the specification.

M.P.E.P. § 2163, subpart (I)(A), first paragraph clearly states: "There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed." (citation omitted)

Claims 18-21 of the present divisional application are identical to Claims 18-21 of the "parent" application, S.N. 09/296,351, filed April 22, 1999. They are also identical to Claims 18-21 of the "grandparent" application, S.N. 60/126,431, filed April 29, 1998.

The Claims in question are identical to the corresponding Claims as filed in the original priority application. Not one word has been changed. Thus each of these Claims continues to be entitled to the "strong presumption" of M.P.E.P. § 2163 that an adequate written description is present. With all respect, the March 26, 2003 Office Action did nothing to rebut this strong presumption. To the contrary, the March 26, 2003 Office Action neither mentioned the strong presumption, nor offered any reasons why the presumption was said to be overcome.

The Applicants are entitled to rely on the strong presumption that the written description requirement is satisfied for all Claims as originally filed. Until the Office rebuts this presumption, the Applicants should have no obligation to respond further to overcome this ground of rejection.

But for sake of completeness, and in the event that prosecution of this application might thereby be accelerated, below are given some examples of portions of the specification where support for these Claims may be found. (Applicants emphasize that the following listings are examples only. In the interest of brevity, no attempt has been made to be thorough.)

Claim 18: Page 6, lines 20-21; Page 33, lines 9-19; and Page 34, new paragraph added by amendment between lines 14 and 15. (This last item merely adds text to the specification to conform to Claims 18 and 19 as originally filed, and therefore does not constitute new matter.)

Claim 19: New paragraph added by amendment between lines 14 and 15.

Claim 20: Page 33, lines 20-24.

Claim 21: Page 33, lines 25-31.

Some Remarks Concerning Issued Patent 6,270,640

The "parent" application has now issued as U.S. Patent 6,270,640. The limitations to which the Office has objected in the present application generally have one or more counterparts in the limitations of the issued claims of the '640 patent. See, e.g., Claims 1, 11, 12, and 13 of the '640 patent. (Applicant is not suggesting that the claim scope is identical, but rather that the limitations in question in the present application generally have counterpart limitations in the claims of the issued patent.)

The Office has previously determined that the Claims of the '640 patent are patentable, which means among other things that each of those Claims is supported by an adequate written description. By analogy, it should follow that the limitations at issue in the present application are also supported by an adequate written description.

Written description summary

It is respectfully submitted that the written description rejection should be withdrawn.

The §§ 102 and 103 Rejections

All pending Claims (with the possible exception of Claim 20) were rejected as being anticipated by Billiot under 35 U.S.C. § 102(a); or as being obvious over a proposed combination of Billot and Daly under 35 U.S.C. § 103(a).

The Office's remarks concerning Claim 20 are not understood. It is not clear whether the Office also intended to reject Claim 20 as being anticipated by Billiot.

The enclosed Affidavit of inventor Isiah Warner removes the Billiot paper as a reference, in that Billiot represents a publication of the inventors' own work, published less than twelve months before the priority date to which this application is entitled under 35 U.S.C. §§ 120 and 119(e).

The date of publication shown on the face of the Billiot paper is April 1, 1998. A note on the bottom left of page 1375 states that the paper was published on the Web on February 26, 1998. Both of these dates are less than one year before the April 29, 1998 priority date to which this application is entitled under 35 U.S.C. § 119(e).

The provisional priority application, S.N. 60/126,431, had a disclosure that is essentially identical to that of the present application, and a filing date of April 29, 1998, within one year of the earliest publication of the Billiot paper. Thus the Billiot paper may be removed as a reference by showing that it is a publication of the inventors' own work.

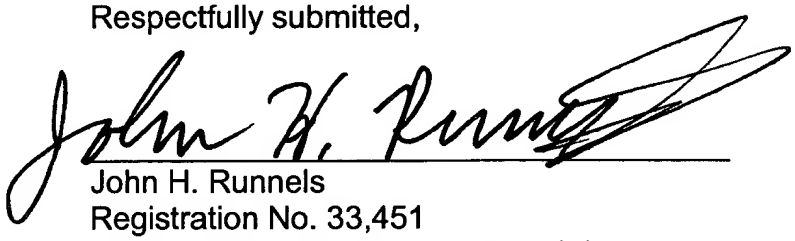
The enclosed affidavit of Dr. Warner, particularly paragraphs 2-4, establishes that the Billiot paper was in fact a publication of the inventors' own work, and explains why Dr. Macossay was named as an author on the paper, but is not named as an inventor in the present application.

It is respectfully submitted that the Billiot paper has thus been removed as a reference, and that all prior art rejections should therefore be withdrawn.

Conclusion

Allowance of Claims 18-23, and 45-53 at an early date is respectfully requested.

Respectfully submitted,



John H. Runnels
Registration No. 33,451
Taylor, Porter, Brooks & Phillips, L.L.P.
P.O. Box 2471
Baton Rouge, Louisiana 70821
(225) 387-3221

September 23, 2003

Appendix A – Amendments to Specification

At page 1, line 8, please amend the paragraph added by the June 7, 2001 Preliminary Amendment as follows:

This is a divisional of copending application serial number 09/296,351, filed April 22, 1999, now ~~allowed with the issue fee paid;~~ U.S. patent 6,270,640; which claims the benefit of the April 29, 1998 filing date of provisional application 60/126,431 under 35 U.S.C. § 119(e).

On page 34, between lines 14 and 15, please insert the following new paragraph:

An example of the present invention is a polymerized dipeptide chiral micelle; wherein said polymerized dipeptide chiral micelle is not a polymer of a compound selected from the group consisting of *N*-undec-10'-enoyl-L-prolyl-L-glutamic acid, *N*-undec-10'-enoyl-L-methionyl-L-glutamic acid, and *N*-undec-10'-enoyl-L-phenylalanyl-β-alanine. Another example of the present invention is a polymerized dipeptide chiral micelle as just described, wherein said micelle comprises a polymer of monomers, wherein each of said monomers comprises an unsaturated hydrocarbon chain linked to a chiral dipeptide.

Appendix B – Amended Claims

1 - 17. (canceled)

18. (original) A polymerized dipeptide chiral micelle; wherein said polymerized dipeptide chiral micelle is not a polymer of a compound selected from the group consisting of *N*-undec-10'-enoyl-L-prolyl-L-glutamic acid, *N*-undec-10'-enoyl-L-methionyl-L-glutamic acid, and *N*-undec-10'-enoyl-L-phenylalanyl-β-alanine.

19. (original) A micelle as recited in Claim 18, wherein said micelle comprises a polymer of monomers, wherein each of said monomers comprises an unsaturated hydrocarbon chain linked to a chiral dipeptide.

20. (original) A composition of matter comprising a mixture of a plurality of different polymerized chiral micelles, wherein each of said polymerized chiral micelles is a micelle as recited in Claim 18.

21. (original) A micelle as recited in Claim 18, wherein said micelle comprises a co-polymer of a plurality of different dipeptide chiral surfactant monomers.

22. (original) A micelle as recited in Claim 18, wherein said micelle comprises a reversed polymerized chiral micelle.

23. (original) A micelle as recited in Claim 18, wherein said micelle comprises poly (sodium N-undecylenyl-L-valine-L-valine), or poly (sodium N-undecylenyl-D-valine-D-valine), or poly (sodium N-undecylenyl-L-leucine-L-leucine), or poly (sodium N-undecylenyl-D-leucine-D-leucine), or poly (sodium N-undecylenyl-L-leucine-L-valine), or poly (sodium N-undecylenyl-D-leucine-D-valine), or poly (sodium N-undecylenyl-L-valine-L-leucine), or poly (sodium N-undecylenyl-D-valine-D-leucine).

24 - 44. (canceled)

45. (previously presented) A compound selected from the group consisting of sodium N-undecylenyl-L-valine-L-valine; sodium N-undecylenyl-D-valine-D-valine; sodium N-undecylenyl-L-leucine-L-leucine; sodium N-undecylenyl-D-leucine-D-leucine; sodium N-undecylenyl-L-leucine-L-valine; sodium N-undecylenyl-D-leucine-D-valine; sodium N-undecylenyl-L-valine-L-leucine; and sodium N-undecylenyl-D-valine-D-leucine.

46. (previously presented) A compound as recited in Claim 45, wherein said compound is sodium N-undecylenyl-L-valine-L-valine.

47. (previously presented) A compound as recited in Claim 45, wherein said compound is sodium N-undecylenyl-D-valine-D-valine.

48. (previously presented) A compound as recited in Claim 45, wherein said compound is sodium N-undecylenyl-L-leucine-L-leucine.

49. (previously presented) A compound as recited in Claim 45, wherein said compound is sodium N-undecylenyl-D-leucine-D-leucine.

50. (previously presented) A compound as recited in Claim 45, wherein said compound is sodium N-undecylenyl-L-leucine-L-valine.

51. (previously presented) A compound as recited in Claim 45, wherein said compound is sodium N-undecylenyl-D-leucine-D-valine.

52. (previously presented) A compound as recited in Claim 45, wherein said compound is sodium N-undecylenyl-L-valine-L-leucine.

53. (previously presented) A compound as recited in Claim 45, wherein said compound is sodium N-undecylenyl-D-valine-D-leucine.